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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/535,005	03/23/2000	William S. Bess	PD A0000259-03EJF	1060

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EXAMINER	
PESELEV, ELLI	

ART UNIT	PAPER NUMBER
1623	

DATE MAILED: 09/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/535,005	BESS ET AL.	
	Examiner	Art Unit	
	Elli Peselev	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 July 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4, 14--19, 21, 22, 25-29 and 33-39* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,14-19,21,22,25-29 and 33-39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Claims 25 –27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The method claims 25-27 are indefinite in that said methods depend from claim 1 which has been limited to the taste masking agent being an ion exchange resin. However, it is not clear from claims 25-26 if the said claims are limited to the taste masking agent being an ion exchange resin. The method claims are also indefinite in that it is unclear from the claims when a drug-resin complex is added.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-4, 14-19, 21, 22 , 25-29 and 33-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eichman (U.S. Patent No. 5,980,882) in combination with Ozaki et al (U.S. Patent No. 5,411,945) or Schiraldi et al (U.S. Patent No. 4,713,243)

Eichman discloses a drug-resin complex which may be coated with a film (column 12, lines 62-67 and column 13) but does not disclose said complex in the form of an orally consumable solid film wherein the film forming compound is pullulan or hydroxypropyl cellulose. However, since Ozaki et al disclose that pullulan can be used as a film for pharmaceuticals, and Schiraldi et al disclose a pharmaceutical film which can adhere to a wet mucous surface containing a pharmaceutical agent and hydroxypropyl cellulose, a person having ordinary skill in the art at the time the instant invention was made would have been motivated to use pullulan or hydroxypropylcellulose as a film forming ingredient for the complex disclosed by Eichman.

Applicant's amendment filed July 26, 2004 has been considered but has not been found persuasive.

Note that terminology "an orally consumable film" (claim 1) encompasses the drug-resin complex coated with a film disclosed by Eichman.

The comparative examples on pages 22-27 of the specification have been considered. Said examples are limited to the use of dextromethorphan as an active agent and the use of pullulan as a film forming agent. However, only claims 21-22 have been limited to said agents and it cannot be predicted if additional agents encompassed by the instant claims will result in a film having desired property. Further, Eichman

discloses that complexing drug with a resin improves its taste and compression and dissolutin characteristics (column 4, lines 24-32). Thus results obtained by the Examples set forth in the specification i.e. the film that is not gritty and pleasant tasting are to expected from the teaching by Eichman i.e. a product that has improved dissolution characteristics would be expected to be less gritty and a product that has a taste masking agent would be expected to be more pleasant tasting.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-4, 14-19, 21, 22, 28, 29 and 33-39 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-20 of U.S. Patent No. 6,596,298 in view of Eichman (U.S. Patent No. 5,980,882). The claims of the U.S. Patent No. 6,596,298 are directed to a consumable film that adheres to and dissolves in a mouth of a consumer containing a pharmaceutical drug The only difference between the claimed compositions and the patented compositions is the use of a drug-resin complex instead of the drug. However, since the drug-resin complex was well known in the art at the time the instant invention

as disclosed by Eichman, a person having ordinary skill in the art at the time the instant invention was made would have been motivated to substitute drug-resin complex to the drug in the patented compositions.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elli Peselev whose telephone number is (571) 272-0659. The examiner can normally be reached on 9.00-5.30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Wilson can be reached on (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Elli Peselev

ELLI PESELEV
PRIMARY EXAMINER
GROUP 1800